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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,776	12/17/2004	Hideaki Sasagawa	TOYA107.005APC	5644

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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08/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/518,776	Applicant(s) SASAGAWA ET AL.	
	Examiner Donna Jagoe	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,8-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8-12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4, 8-12 and 15-18 are pending in this application.

Applicants' arguments filed May 4, 2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 8-12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. WO 97/02821 A2 and Godbey et al. Patent Application Publication US 2002/0187181 A1

The claims are drawn to a pharmaceutical composition comprising the antifungal agent of figures (1) and (2) combined with (A) a film forming agent selected from *inter alia*, ethyl cellulose and (B) a water soluble plasticizer in a form of a solid or a paste at 20°C (68°F or approximately normal room temperature) at 1 atm (normal atmospheric pressure) selected from a polymer or copolymer of oxyethylene and/or oxypropylene and has a polymerization degree of 70 or more. Examples of these film forming agents and plasticizers are provided in the instant specification as "Eudragit" (film-forming agent)" and "Pluronic F68" (plasticizer).

Kodama et al. teach the antifungal agents in figures (1) and (2) (see entire document) for topical application (page 11, lines 14-15). Addressing instant claim 17, examples are provided where the composition is applied to the soles of guinea pigs (page 22, lines 11-22) and provides an example wherein a liquid preparation is applied

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by painting (page 18, Formulation example 5). Kodama et al. does not teach the specific film forming agents and plasticizers instantly claimed.

Godbey et al. teach a composition comprising a water soluble polymer and plasticizer as a carrier (see abstract) for delivering pharmaceuticals to skin or nails (paragraph 7). The polymeric film can be polyacrylate (an acrylic resin) (see claim 4 and claim 31) and a plasticizer such as a random copolymer of ethylene oxide and propylene oxide or block copolymer of ethylene oxide and propylene oxide such as Pluronic (paragraph 26). Applicant's specification teaches that Pluronic meets the limitations of the plasticizer in instant claims 1 and 18. The amount of plasticizer present in the carrier recited is from about 1% to about 40% (paragraph 27) which encompasses the claimed amount of 1 to 10 folds with respect to the content of the film forming agent of instant claim 1. The active agent includes antifungal agents (paragraph 47) for delivery to fingernails or toenails or treatment to the skin with antifungal agents (paragraph 50). Addressing instant claims 9 and 10, drawn to the further inclusion of an anionic surfactant, Godbey et al. teach the inclusion of a surfactant such as an anionic surfactant (paragraph 40). Specific surfactants include, without limitation, C8 to C22 alkyl ether ethoxylates, C8 to C22 alkyl ester ethoxylates, sorbitol C8-C22 alkyl esters, sorbitol C8 to C22 alkyl ester ethoxylates, and mixtures including one or more of the foregoing. Godbey et al. does not specifically teach acetone as a further organic solvent, however, it teaches an organic solvent. (paragraph 39 and claim 40). Acetone is a well-known solvent for diluting nail varnish and it would have been obvious to one having ordinary skill in the art to employ acetone as a solvent

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in the composition. Godbey et al. does not teach an antifungal composition wherein the antifungal composition is capable of "recoating" (claim 15) however, Kodama et al. teach the antifungal medicament of formula (1) and (2) for painting (page 18, example 5) and Godbey et al. teach the same carrier in a film for coating nails or skin. It does not teach recoating, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to recoat (repaint) the formulation when necessary to reapply an antifungal film for effective treatment. Regarding the antifungal medicinal composition wherein the coating is removable by swelling means or physical scratching, none of the references teach this limitation, however, Godbey et al. teach that the formulation is a water soluble or water dispersible film (paragraph 32) and as such would be swellable and is capable of being removed by physical scratching. Although Godbey et al. does not teach that the composition forms a "viscous glass state" as in instant claims 1 and 18, Godbey et al. teach application to fingernails and toenails and further teach decorative colorings or appliques by be delivered with the claimed device. It would have been obvious to one having ordinary skill in the art that a film for treatment to the fingernails and toenails would dry in a viscous glass state motivated by the knowledge of one skilled in the art that medicated film painted on the nails is expected to dry so that the treatment composition remains in place for maximal effectiveness. Further, with the inclusion of decorative colorings in the composition of Godbey et al., it appears to be a nail polish which also dries to a viscous glass state.

One having ordinary skill in the art could have substituted the antifungal agent used for topical application and for "painting" recited in Kodama et al. for the antifungal

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agent of Godbey et al. in the polymer/plasticizer composition for painting, and the results of the substitution would have been predictable. It would have been prima facie obvious to substitute one antifungal agent for the other. Express suggestion to substitute one antifungal for another need not be present to render such substitution obvious. Godbey et al. teach an effective film-forming carrier for antifungal agents for application to skin and nails. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the antifungal agent taught in Kodama et al. for the antifungal agent of Godbey et al in the film-forming agent/plasticizer for the predictable result of effective treatment of nail fungus or skin fungus.

No claims are allowed.

Response to Arguments

Applicant's arguments with respect to claims 1, 4, 8-12 and 15-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./
Examiner
Art Unit 1619

July 15, 2010